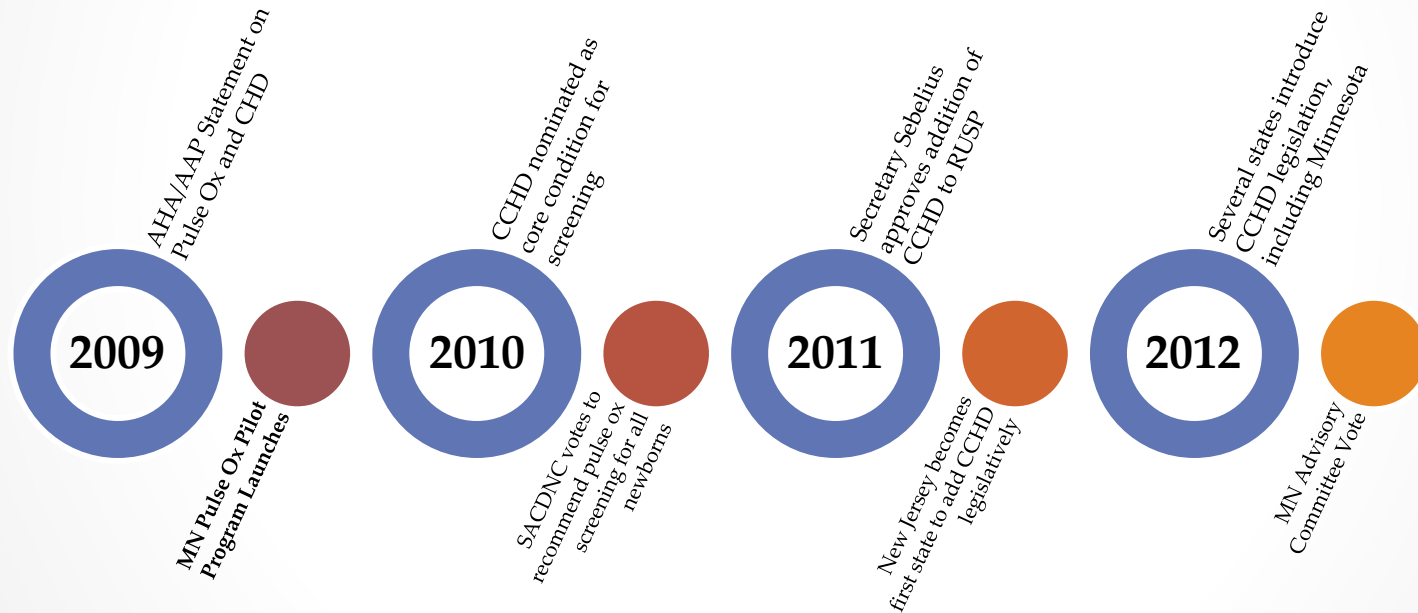


Point-of-Care Screening for CCHD in Minnesota: Approval, Legislation, and Implementation

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History of CCHD Work in Minnesota



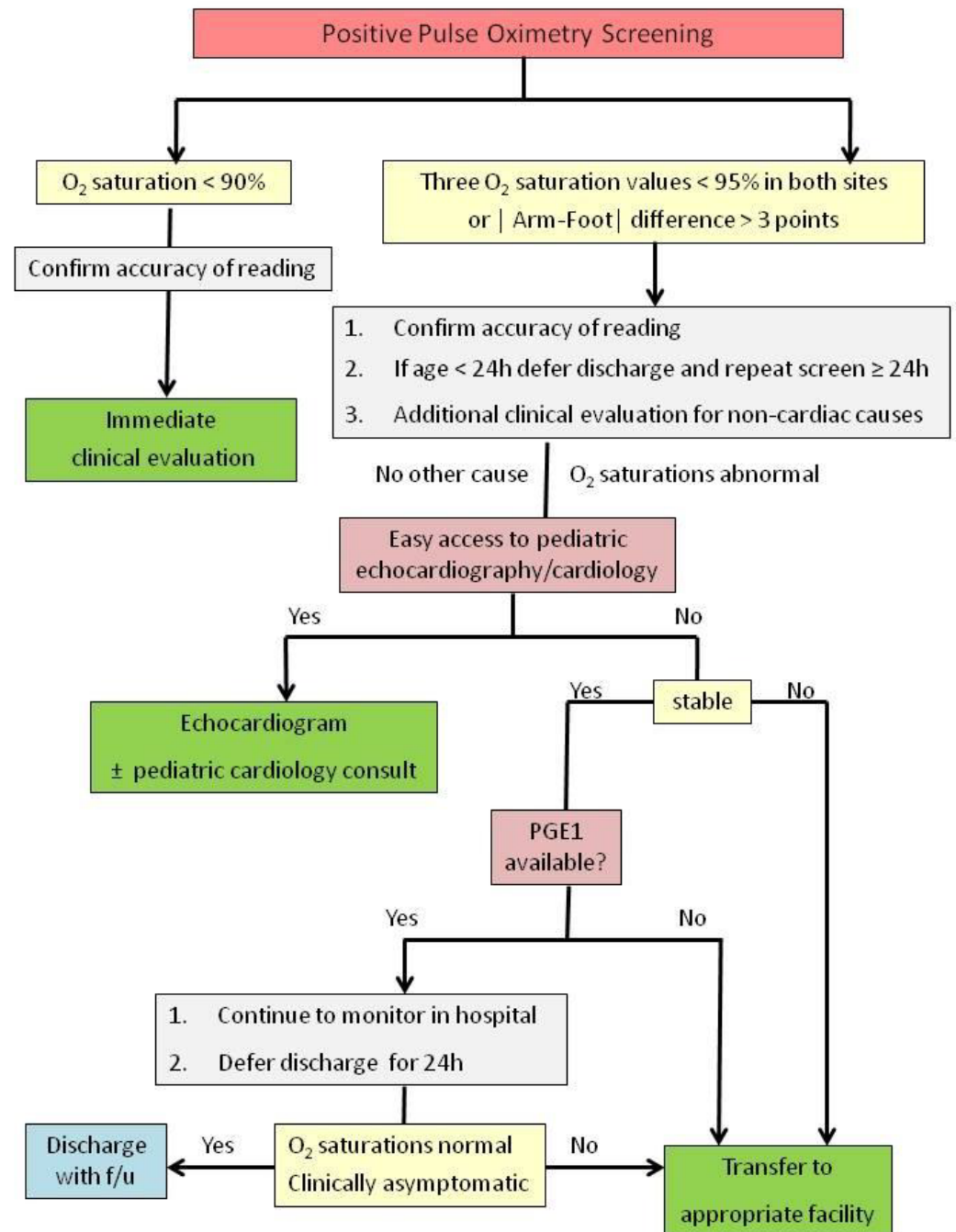
Advisory Committee

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Role of MDH

- Collaboration between Short Term Follow-Up (PHL), Birth Defects Monitoring and Analysis (CYSHN), and Long Term Follow-Up (CYSHN)
- Role for State Health Programs
 - Monitor process from pulse oximetry to echo to surgery (as needed)
 - Provide guidance and quality indicators to facilities and providers performing pulse oximetry
 - Educate and train facilities and providers as necessary
 - Provide resources and support to families and children with a CCHD
 - Provide state-wide surveillance of CCHDs

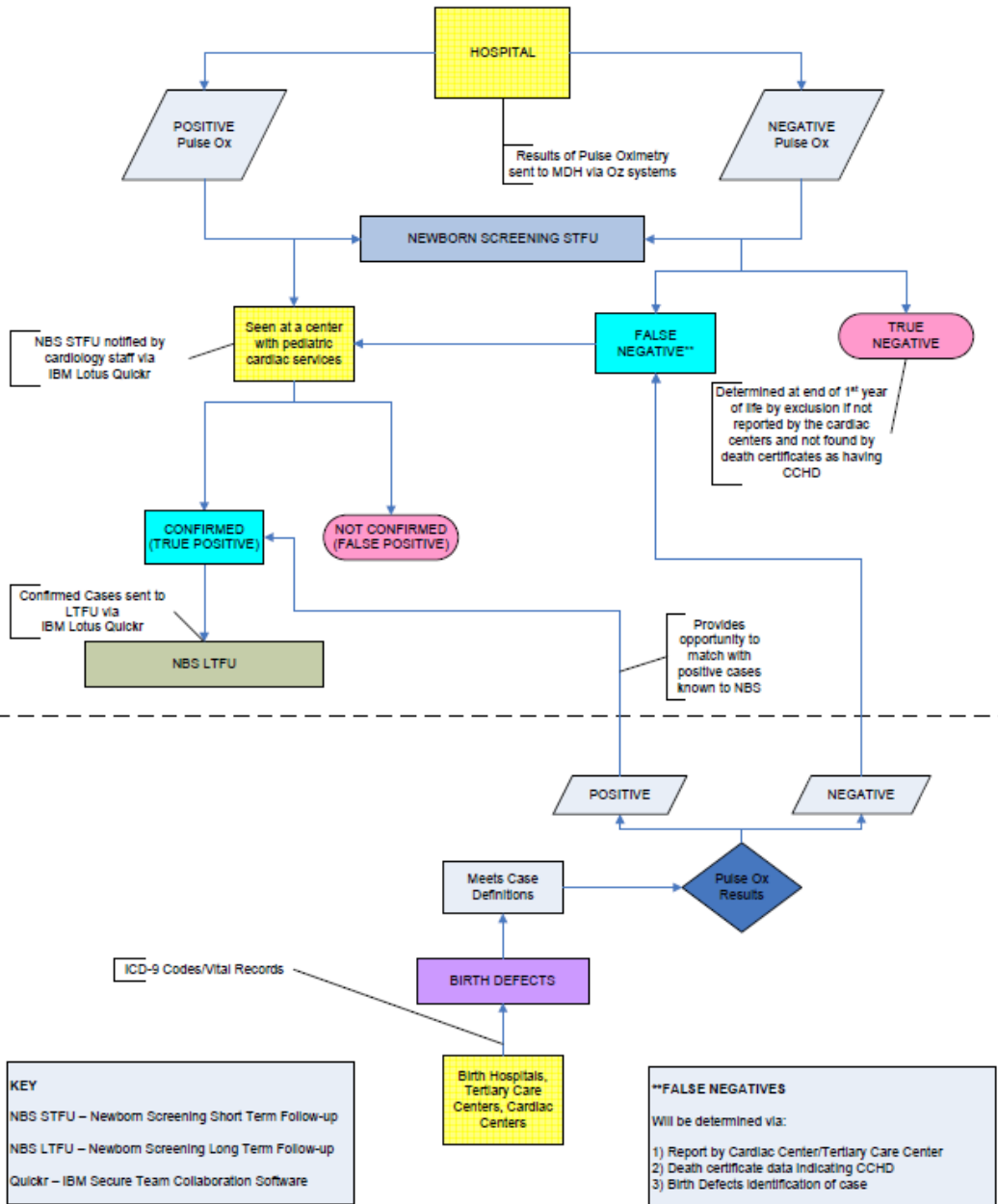
Action Plan for Positive Results



Result Reporting

- Secure Result Reporting Infrastructure
 - Direct method of result transport from hospital to MDH
 - “Real-time” reporting of pulse oximetry results for all hospitals and birthing centers
 - Raw data of pulse oximetry results will be requested
 - The degree to which screening supports early detection of CCHD
 - What types of CCHD are being detected – and at what values
 - Which hospitals may be struggling with implementation

Figure 5: Information flow within the MDH Newborn Screening Program for CCHD.



Short Term Follow-Up

MN Monitors 46 Conditions

Cardiac Conditions

- Aortic Valve Stenosis
- Atrial Septal Defect (ASD) (PFO)
- Coarctation of the Aorta
- Common Truncus
- Ebstein's Anomaly
- Endocardial Cushion Defect (AV)
- Hypoplastic Left Heart Syndrome
- Patent Ductus Arteriosus (PDA)
- Pulmonary Valve Atresia and Stenosis
- Single Ventricle
- Tetralogy of Fallot
- Transposition of the Great Arteries
- Tricuspid Valve Atresia and Stenosis
- Ventricular Septal Defect (VSD)

Central Nervous System Conditions

- Anencephalus
- Encephalocele
- Hydrocephalus
- Microcephalus
- Spina Bifida

Chromosome Conditions

- Down Syndrome
- Trisomy 13
- Trisomy 18

Eye Conditions

- Aniridia
- Anophthalmia and Microphthalmia
- Congenital Cataract

Cardiac Conditions

- Aortic Valve Stenosis
- Atrial Septal Defect (ASD) (PFO)
- Coarctation of the Aorta
- Common Truncus**
- Ebstein's Anomaly
- Endocardial Cushion Defect (AV Canal)
- Hypoplastic Left Heart Syndrome**
- Patent Ductus Arteriosus (PDA)
- Single Ventricle
- Pulmonary Valve Atresia & Stenosis**
- Tetralogy of Fallot**
- Transposition of the Great Arteries**
- Tricuspid Valve Atresia and Stenosis**
- Ventricular Septal Defect (VSD)
- Total Anomalous Pulmonary Venous Return (TAPVR)**

Other Health Conditions

- Fetal Alcohol Syndrome (FAS)

Estimated Number of Cases of CCHD in Minnesota

Critical Congenital Heart Defects	Estimated Expected Annual Case Count*	
	Estimated from all cases identified in BDIS, regardless of maternal residence 2006-2009	Estimated using rates from Hennepin/Ramsey Counties only, 2006-2009
Hypoplastic Left Heart Syndrome	16	13
Pulmonary Atresia	41	40
Tetralogy of Fallot	30	34
Total Anomalous Pulmonary Venous Return	N/A	N/A
Transposition of the Great Arteries	34	32
Tricuspid Valve Atresia & Stenosis	5	5
Truncus Arteriosus	5	4
Total CCHD, excluding TAPVR	131	128
* One child may have more than one of these defects and may be counted twice.		
Total number of children with CCHD, excluding TAPVR	114	116

Role of Long Term Follow-Up of CCHD

- Facilitate connection to all available services
 - Multi-disciplinary health care
 - Community-based resources
 - Public and private funding for medical services
 - Family-to-family and support group connections
 - Developmental monitoring and early intervention services
- Periodic follow up to monitor health and wellbeing
- Maintaining a tracking system for collecting data on health outcomes
- Evaluation of the efficacy of services and newborn screening system for CCHD

Role of MN BDMAP in Surveillance of CCHD

- Collection of clinical information from medical records on confirmed CCHD cases
 - Presenting prenatally, at clinical exam, by pulse ox, with clinical symptoms, or at autopsy
- Monitoring of health outcomes of CCHD cases
- Referral of cases to LPH agencies for care coordination and referral to services
- Identification of false negative CCHD screening cases
 - Cases not identified by pulse ox screening
- Evaluation of systems effectiveness

Cost Estimates for MDH

- Proposed Fee Increase of \$6 per specimen for the addition of CCHD

Breakdown	
Personnel	
Total	\$146,000
Training and Education	
Total	\$50,000
Results Reporting Infrastructure	
Total	\$100,000
Telehealth and Indirect	
Total	\$100,000
Total Expenses	
	\$396,000
Cost per Baby*	\$6

Cost Estimates to Hospital

- Preliminary cost analysis from pilot studies (Ridges)
- Upfront cost of \$300 per reusable probes for pulse ox
 - Serves ~ 1,000 patients
- Probe straps = \$1.20 per patient
- Nursing time = 5-10 minutes, including education
 - ~\$6.10-\$9.25 per patient
- Total gross cost to hospital ~\$7.50-\$11 per infant

It's Been Approved...

...

... Is Legislation still
Necessary?

Know Your Statute

- Most Newborn Screening statutes are *LAB* specific
 - Result Reporting is typically only covered from the standpoint of lab reporting results to providers
- What can your fees cover?
 - Some statutes specify only “lab-based testing”
- Ensure explicit authority

Working with Advocates

- Cooperation!
 - Merging advocates desires with program needs
- Precedent
 - Look at other areas that may inform appropriate language (birth defects registries, EHDI, etc.)
- Legislative advocacy
 - Set-up pulse oximetry “show and tell”
- Bipartisan support
 - Always helps!



MN Statute

1

MINNESOTA STATUTES 2013

144.1251

144.1251 NEWBORN SCREENING FOR CRITICAL CONGENITAL HEART DISEASE (CCHD).

Subdivision 1. **Required testing and reporting.** (a) Each licensed hospital or state-licensed birthing center or facility that provides maternity and newborn care services shall provide screening for congenital heart disease to all newborns prior to discharge using pulse oximetry screening. The screening must occur after the infant is 24 hours old, before discharge from the nursery. If discharge occurs before the infant is 24 hours old, the screening must occur as close as possible to the time of discharge.

(b) For premature infants (less than 36 weeks of gestation) and infants admitted to a higher-level nursery (special care or intensive care), pulse oximetry must be performed when medically appropriate prior to discharge.

(c) Results of the screening must be reported to the Department of Health.

Subd. 2. **Implementation.** The Department of Health shall:

(1) communicate the screening protocol requirements;

(2) make information and forms available to the hospitals, birthing centers, and other facilities that are required to provide the screening; health care providers who provide prenatal care and care to newborns; and expectant parents and parents of newborns. The information and forms must include screening protocol and reporting requirements and parental options;

(3) provide training to ensure compliance with and appropriate implementation of the screening;

(4) establish the mechanism for the required data collection and reporting of screening and follow-up diagnostic results to the Department of Health according to the Department of Health's recommendations;

(5) coordinate the implementation of universal standardized screening;

(6) act as a resource for providers as the screening program is implemented, and in consultation with the Advisory Committee on Heritable and Congenital Disorders, develop and implement policies for early medical and developmental intervention services and long-term follow-up services for children and their families identified with a CCHD; and

(7) comply with sections 144.125 to 144.128.

History: 2013 c 108 art 12 s 15